Issuing Department: Human Subjects Protection Program
Policy Number: 2011-009.11
Policy Title: Institutional Review Board – Studies Conducted in Foreign Locations

Purpose

The purpose of this policy is to ensure that subjects who enroll in studies conducted in foreign locations are provided with equivalent protections.

Definitions

Policy

Research conducted by UConn Health investigators in foreign countries remains under UConn Health purview and guidelines. While some adjustments may be made to some requirements to respect cultural differences, standards for ethical conduct are not relaxed. In addition, if identifiable protected health information is brought back to UConn Health, HIPAA must be addressed.

Research projects must have been approved by the local equivalent of an IRB before the UConn Health IRB will grant final approval. Where there is no equivalent board or group, investigators may rely on local experts or community leaders to provide approval. There must also be detailed plans in place for local monitoring of studies that pose more than minimal risk to subjects. If the IRB is not satisfied with the review of local experts and/or the plans for monitoring there is the possibility that the study will not be approved. Such determinations would be made by the convened board.

Researchers must describe what, if any, knowledge or experience they possess regarding the language and culture of the country in which the research is to be conducted.

The IRB may seek guidance from the Office for Human Research Protection (OHRP) to determine whether procedures described by a foreign institution afford protections that are at least equivalent to U.S. regulations and may be substituted for the US regulations. If OHRP finds the foreign guidelines are found to be equivalent to U.S. regulations, the investigator is permitted to substitute those foreign procedures.

Studies conducted in foreign locations are also subject to audit by the Research Compliance Monitor (RCM). The RCM may require the investigator to provide copies of or access to all research related records such that the audit may occur. Only in extreme extenuating circumstances would the RCM visit a foreign location. Investigators continue to be obligated to report issues of noncompliance and unanticipated problems to the IRB and to provide participants with a mechanism for expressing complaints or concerns.

Procedure

When preparing a submission to the IRB the PI is directed to:

- provide documentation of local approval,
- provide documentation of the authority and expertise of the individual or group who granted approval,
- provide plans for local monitoring for studies involving more than minimal risk,

- describe their knowledge of language and culture of the location where the research will be conducted.

The IRB staff screen the submission and the IRB reviews the study in accordance with policies and procedures for conducting IRB reviews, including requirements for consent and translation of documents.

Complaints, concerns and reports of noncompliance and/or unanticipated problems involving risk will be reviewed by the IRB in accordance with existing policies.

The IRB will communicate and coordinate with the local IRB or ethics board as needed when appropriate.

Related Policies

2009-001.0 – Reporting Unanticipated Problems to the IRB
2009-002.0 – Reporting Non-Compliance to the IRB
2009-005.0 – Monitoring of IRB Approved Studies
2011-009.2 – Institutional Review Board – Exemptions
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board
2011-018.0 – Complaints, Concerns, Suggestions

Basis

45 CFR 46

Document Attributes

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Reviewed and Approved By:

Richard H. Simon **11/01/23**

Richard Simon, MD **Date**
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